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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

July 9, 1998

Ref: 98-DAL-WL-#43

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Ron Overstreet, President
Sunrise Farms, Inc.
P.O. Box 787
Boise City, Oklahoma 73933

Dear Mr. Overstreet:

An investigation of your dairy operation on February 23, 1998, confirmed that you sold a cow to a slaughter buyer on November 12, 1997, which was subsequently offered for sale for slaughter as food on November 13, 1997, in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). A food is adulterated if it bears or contains a new animal drug (or conversion product thereof) which is unsafe within the meaning of Section 512 of the Act [Section 402(a)(2)(C)(ii)]. In addition, your extra-label use of Penicillin G Procaine injection in a manner other than in accord with its labeling, or other than in accord with a veterinarian's prescribed order causes the drug to be adulterated under Section 501(a)(5) of the Act.

On November 12, 1997, you sold animal #8012 to Mr. Keith Lauer, Buyer for Tri-State Livestock, Texhoma, OK. On November 13, 1997, the animal was offered for slaughter as food at Booker Packing Company, Inc., Hwy 15 East, Booker, TX. USDA analysis (Laboratory Report #377550) of tissue samples collected from this animal identified the presence of penicillin at 0.09 parts per million (ppm) in the kidney tissue. A tolerance of 0.05 ppm has been established for residues of penicillin in the edible tissues of cattle (Title 21, Code of Federal Regulations, Part 556.510). The presence of this drug in edible tissue from this animal causes the food to be adulterated [402(a)(2)(C)(ii)].

Our investigation found that you hold animals under conditions which are so inadequate that diseased animals and/or medicated animals bearing potentially

harmful drug residues are likely to enter the food supply. You do not have an adequate system for assuring that animals administered drugs by your firm, or by an attending veterinarian have met the required preslaughter withdrawal period to permit depletion of potentially hazardous residues of drugs from edible tissues. Additionally, you do not have a system for documenting that the purchaser of a medicated animal has been informed of a required preslaughter withdrawal period. Food from animals held under such conditions is adulterated [Section 402(a)(4)].

You sold animal #8012 to a known slaughter buyer, following a high dosage treatment of the animal with penicillin in an extra-label manner on November 8/11, 1997, as prescribed by Dr. N. Mark Reif, D.V.M. Medicating the animal using penicillin in the treatment of a uterine infection was ordered by Dr. Reif, who also established a Treatment Schedule. The Treatment Schedule instructs your firm to withdraw the penicillin treatment from the animal for a period of 14 days prior to slaughter. Your firm failed to observe the withdrawal instructions following the use of the penicillin drug, and failed to provide the withdrawal requirement to the slaughter buyer causing the adulteration of the food.

By assuming the responsibility of administering the penicillin injection in an extra-label manner, as prescribed by Dr. Reif, which results in the adulteration of the animal, you share in the responsibility for the violative tissue residue. Your firm's failure to follow the Treatment Schedule for withdrawal and failure to follow the suggested milk and slaughter residue test instructions also served to adulterate the drug, in violation of Section 501(a)(5) of the Act.

The above is not intended to be an all-inclusive list of violations. As a dairy producer selling animals to slaughter buyers which may be offered for sale for slaughter as food, you are responsible for assuring that your overall operation and the food you distribute are in compliance with the law. This responsibility includes taking the necessary precautions to assure that violative drug residues do not occur in animals treated on the dairy or by, or on the order of an attending veterinarian. Failure to take prompt action to correct the above violations and to establish procedures, whereby such violations do not recur may result in regulatory action without further notice such as seizure and/or injunction.

You should notify this office, in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of

similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed. Also include copies of any available documentation demonstrating that corrections have been made.

Your reply should be sent to James R. Lahar, Compliance Officer, at the above letterhead address.

Sincerely,

Robert D. Deininger for

Joseph R. Baca
Dallas District Director

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